HFZ-35-pwsch 4/3/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

454

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Richard A. Piccolo
President
RichMark International Corporation
48 Malta Commons, Suite 47-48
Ballston Spa, 12020
Malta, New York 12020

Re: Rejuveness Silicone
Elastomer for Scar
Management, K953420

Dear Mr. Piccolo:

The Food and Drug Administration (FDA) has reviewed promotional materials for Rejuveness which currently appear both on your web site at the internet address: http://www.rejuveness.com, and in several women's consumer magazines such as Vogue (April, 1997), Shape (June, 1997), Cosmopolitan (July, 1997), and Allure (August, 1997). Rejuveness is manufactured by RichMark International Corporation (RichMark) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Rejuveness has been cleared under section 510(k) of the Act as a soft durable medical grade silicone occlusive sheeting product intended for the management of hypertrophic and keloid scars resulting from burns or scars arising from surgical procedures and traumatic events.

In our previous letter dated January 22, 1997, RichMark was advised that claims for Rejuveness stating that the device can prevent and/or treat scars were uncleared intended uses which would require a new 510(k). Our review of your web site and the magazines identified above indicate that RichMark continues to promote Rejuveness for these and other major modifications in the intended use which have not been cleared by the agency. Your claims for Rejuveness include:

-"Clinically proven 90% effective in treating existing scars and preventing new ones;"

-"It is effective on scars resulting from surgical incisions (i.e., breast reduction, cesareans, open heart surgery, etc.); burns, cystic acne; cuts;" and even stretch marks."

Your 510(k) clearly limits claims for Rejuveness to the management of scars and not their treatment or prevention. Additionally, claims of effectiveness in specific target organs or disease states such as the breast, open heart surgery, cystic acne, and cuts represent a narrowing of the intended use and are not permitted without the filing and clearance of a new 510(k).

We also note that one of the promotional pieces discusses the mechanism of action for Rejuveness and states, "The electrostatic ionic bonding process actually rebuilds skin from the inside out." Before RichMark can make such a claim, it must be supported to the agency by data. Your 510(k) does not contain any data to support this claim .

Rejuveness is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

Rejuveness is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use(s) of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Rejuveness Elastomer. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New York District Office (HFR-NE100), 850 Third Avenue, Brooklyn, New York 11232-1593.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health